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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDERSON, REBECCA L	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,927	SMITH ET AL.	
	Examiner	Art Unit	
	Rebecca L Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6 and 20-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 6 and 20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 5, 6 and 20-28 are currently pending in the instant application and are rejected.

Response to Amendment

Applicants amendments to the claims and arguments filed 20 January 2004 have been entered into the application and fully considered.

Applicant has amended the claims by canceling claims 7-19, adding new claim 28 and amending claims 21, 23, 25, 26 and 27. The cancellation of claims 7-19 has cancelled all withdrawn claims in the instant application. Newly added claim 28 is newly included in the enablement rejection of claims 23-25. The amendment to claim 21 has not overcome the 35 USC 112 rejection of the claim. The amendment to claims 23 and 25 has not overcome the 35 USC 112 enablement rejection of the claims. The amendment to claims 26 and applicants support for the well-known term "AB" as meaning "amyloid B" has overcome the 35 USC 112 1st paragraph rejection of the claim and the 2nd paragraph indefinite rejection of the claim, however, the amendment has introduced an enablement rejection of the claim. The amendment to claim 27 has overcome the 35 USC 102(b) rejection of claims 27, 5 and 6 over NEGISHI ET AL. but has not overcome the 35 USC 102(b) rejection of the claims 27, 5 and 20 over LINFIELD ET AL. and has introduced a new 103(a) rejection of claims 27, 5, 6 and 20 and has introduced a new 112 rejection of claim 5.

Applicant's arguments filed 20 January 2004 have been fully considered but they are not persuasive.

In regards to applicants arguments of the 35 USC 12 first paragraph rejection of claims 23-25, applicant argues that the current state of the art clearly demonstrates that accumulation of amyloid B protein in the brain is a cause of Alzheimer's Disease, that in vitro assays are demonstrative of a method of teting the activity of a particular compound and provides citations to medical journals and US patents to support this. While applicants citations and arguments have overcome the enablement rejection in regards to the treatment of Alzheimer's disease, the arguments have not overcome the enablement rejection in regards to the treatment of all other diseases encompassed by the claims and has not overcome the enablement rejection in regards to the prevention of Alzheimer's disease. While the state of the art reflects that amyloid B is a causative factor in Alzheimer's disease and that preventing or removing amyloid B plaques would provide a treatment for those afflicted with Alzheimer's disease, the instant claims are not directed to only Alzheimer's disease and no further data for the correlation of amyloid B protein to other diseases is found in any of the citations, not anywhere in the instant specification. Therefore, the rejection of claims 23-25 under 35 USC 112 1st paragragh, while providing the for the treatment of Alzheimer's disease, fails to provide for the prevention of Alzheimers diseae or the treatment and prevention of all other diseases encompassed by applicants instant claims 23-25.

In regards to applicants arguments of the 35 USC 112 1st paragraph rejection of claims 21 and 22, applicant argues that it is well-known in the art that by administering a compound that exhibits inhibitory activity of another

compound, that the other compound will likely decrease upon said administration. Similarly, after administering said first compound, if the amount of the administration of the compound is decreased or ceased, an increase in the other compound will likely result and that this is the method of modulation. This argument is not persuasive, since the only data found in the instant specification is for the inhibition of the level of amyloid beta precursor protein and the claims are directed to only the administration of the compounds (not the cessation of administration), which would cause only an inhibitory activity.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation ""substituent(s) on J is(are) independently substituted or unsubstituted alkyl, halogen, ether, -S-alkyl, or –S-aryl, however, there is insufficient antecedent basis for this limitation in the claim since the parent claim 27 recites that J is substituted by one or more substituents selected from the group consisting of methyl, substituted alkyl, halogen, ether, -S-alkyl, or –S-aryl.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-25, 26 (now considered definite) and newly added claim 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of Alzheimer's disease does not reasonably provide enablement for the prevention of Alzheimer's disease or the treatment of any other disease applicant considers mediated by the inhibition of cellular production of amyloid B. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention is the treatment (claim 23) and prevention (claim 25) of all disease conditions (claims 23 and 25) such as amyloid angiopathy, cerebral amyloid angiopathy, systemic amyloidosis, Alzheimer's disease, hereditary cerebral hemorrhage with amyloidosis of the Dutch type and

Down's syndrome (claim 24). Claim 26 is directed to the treatment of a subject in need thereof to decrease production of amyloid B and claim 28 is drawn to a method of modulating the proteolytic cleavage of APP, which would be used for the treatment or prevention of diseases associated with the proteolytic cleavage of APP.

The state of the prior art and the predictablility or lack thereof in the art

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic and preventive effects of all diseases, whether or not the disease is effected by the inhibition of cellular levels of amyloid β would make a difference.

It is the state of the art that there is no known cure or prevention for Alzheimer's disease and that there are only four medications available in the United States available to temporarily slow the early stages of Alzheimer's disease. The current drugs for the treatment of Alzheimer's disease, Aricept, Exelon, Reminyl and Cognex, treat early stages of Alzheimer's disease by delaying the breakdown of acetylcholine. Memantine, which blocks excess amounts of glutamate treats late stage Alzheimer's disease. (URL:http://www.cnn.com/2003/HEALTH/conditions/09/24/alzheimers.drug.ap/index.html).

Hence, in the absence of a showing of correlation between all the diseases claimed as capable of treatment and/or prevention by the inhibition of cellular levels of amyloid β, one of skill in the art is unable to fully predict possible results from the administration of the compound of claim 27 due to the unpredictability of the role of the inhibition of cellular levels of amylid β, and since the treatment of Alzheimer's disease is mediated by the breakdown of acetylcholine or the inhibition of excess amounts of glutamate.

The amount of direction or guidance present and the presence or absence of working examples

The only direction and guidance present in the specification is the suppression of amyloid precursor protein (APP) (page 2) for the inhibition of cellular production of amyloid β, found on pages 312-367. Page 350 and 359 show that some compounds of the present invention are not active for the inhibition of cellular production of amyloid β. Besides the statement on page 10

of the instant specification, which states that APP is believed to be involved in numerous disease states. There is no correlation between the inhibition of cellular production of amyloid β with the prevention of Alzheimer's disease or with the treatment or prevention of all other disease conditions, i.e. the specification is silent and fails to provide guidance as to what diseases are mediated by the inhibition of cellular production of amyloid β.

The breadth of the claims

The breadth of the claims is the treatment of all diseases with the compound of claim 27 (claim 23), the treatment of amyloid angiopathy, cerebral amyloid angiopathy, systemic amyloidosis, Alzheimer's disease, hereditary cerebral hemorrhage with amyloidosis of the Dutch type and Down's syndrome (claim 24), the prevention of all diseases with the compound of claim 27 (claim 25) and the treatment and prevention of all diseases with the compound of claim 27 (claims 26 and 28).

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what diseases out of all diseases would be benefited by the inhibition of amyloid β and would furthermore then have to determine which of the claimed compounds would provide treatment or prevention of the disease.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is

required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the compound of the claim 27 for the treatment or prevention of any disease and only provides for the treatment of Alzheimer's disease. As a result necessitating one of skill to perform an exhaustive search for which diseases can be treated or prevented by what compounds of claim 27 in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search , but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated or prevented by the compound encompassed in the instant claims, with no assurance of success.

This rejection can be overcome deleting the claims.

Claims 21 and 22 and newly added claim 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the inhibition of proteolytic cleavage of amyloid beta precursor protein does not

reasonably provide enablement for the modulating of the level of amyloid beta precursor protein, either by increasing or decreasing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The nature of the invention

The nature of the invention is the modulating of the level of Amyloid Beta Precursor Protein (APP) (claims 21 and 28), specifically APP751, APP695wt, APP670/671, APP670/671/717, sAPP, α-sAPP or β-sAPP (claim 22) with the compound of claim 27.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the

art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face. It is noted that on page 1 of the instant specification it is stated that there is a continuing need in the art for compounds that can specifically inhibit proteolytic cleavage of APP, thereby inhibiting amyloid β protein production.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the suppression of cellular levels of amyloid β, whether or not Amyloid Beta Precursor Protein was increased or decreases would make a difference as to how and if amyloid β could be suppressed.

The amount of direction or guidance present and the presence or absence of working examples.

The amount of direction or guidance present is found on pages 312-367 wherein the suppression of cellular levels of amyloid β by the compounds of the formula as found in claim 27. There is no direction or guidance for the increase or decrease of Amyloid Beta Precursor Protein. The only guidance present is for the inhibition of proteolytic cleavage of APP.

The breadth of the claims

The breadth of the claims is the modulation (increase or decrease) of Amyloid Beta Precursor Protein with the compound of claim 27.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine which compounds of claim 27 increase Amyloid Beta Precursor Protein and which compounds decrease Amyloid Beta Precursor Protein and how this would effect the inhibition of proteolytic cleavage of amyloid β.

The level of the skill in the art.

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity.

Thus, the specification fails to provide sufficient support of the broad use "modulating" the level of Amyloid Beta Precursor Protein with the compound of the claim 27. As a result necessitating one of skill to perform an exhaustive search for which compounds of claim 27 would suppress (inhibit the proteolytic cleavage of APP) and which compounds would increase the level of Amyloid Beta Precursor Protein.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the

art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

It is suggested that these claims be amended to include only the inhibition of the proteolytic cleavage of APP instead of modulating.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27 and 5 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by LINFIELD ET AL. which discloses antibacterially active substituted anilides of carboxylic and sulfonic acids. LINFIELD ET AL. discloses the compound 105, page 1743 in Table IV wherein Ar1 is 4-(n-C3H7)C6H4, R is 4-ClC6H4CH2 and Ar2 is 3,4-Cl2C6H3 which corresponds to applicants instantly claimed invention wherein D is hydrogen, E is phenyl substituted with halogen (chlorine), G is phenyl substituted with a halogen (chlorine) and J is phenyl substituted with alkyl substituted alkyl (n-propyl).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27, 5, 6 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over LINFIELD ET AL.

Determining the scope and contents of the prior art

LINFIELD ET AL. discloses antibacterially active substituted anilides of carboxylic and sulfonic acids. LINFIELD ET AL. discloses the substituted sulfonanilides as found in Table IV, page 1743 and on the second column of

page 1741. The substituted sulfonanilides of page 1741 contain an phenyl substituted with R in the position corresponding to applicants instant variable J. The value for R can be alkyl, alkylaryl or arylalkyl group, R", which corresponds to applicants instant CH(D)-G, can be p-ClC6H4CH2, the phenyl substituted with X and Y corresponds to applicants instant variable E which can be substituted or unsubstituted phenyl. The substituted sulfonanilides in Table IV, contain for AR1, which corresponds to applicants instant J, chlorine substited phenyl (compounds no. 96 and 100), methyl substituted phenyl (compound no. 101). LINFIELD ET AL. discloses the compound 105, page 1743 in Table IV wherein Ar1 is 4-(n-C3H7)C6H4, R is 4-ClC6H4CH2 and Ar2 is 3,4-Cl2C6H3 which corresponds to applicants instantly claimed invention wherein D is hydrogen, E is phenyl substituted with halogen (chlorine), G is phenyl substituted with a halogen (chlorine) and J is phenyl substituted with alkyl substituted alkyl (n-propyl).

Ascertaining the differences between the prior art and the claims at issue.

The difference between the prior art and the claims at issue is that the prior art does not specifically disclose species which correspond to applicants instant invention wherein D is hydrogen, E is phenyl substituted with halogen (chlorine), G is phenyl substituted with a halogen (chlorine) and J is phenyl substituted with methyl or halogen.

Resolving the level of skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art when faced with LINFIELD ET AL. to prepare compounds of the instant invention wherein J is methyl or halogen

substituted phenyl since the prior art provides substituted sulfonanilides which overlap with applicants instantly claimed invention and provides preferences towards substituents in the position equivalent to applicants J wherein, besides the n-propyl substituted phenyl, the substituted sulfonanilides are substituted with chlorine and methyl. One of ordinary skill in the art would be motivated to prepare compounds of the instant invention wherein J is methyl or halogen substituted since the prior art discloses compounds within the instant invention wherein J is n-propyl substituted phenyl, since the prior art discloses other substituted sulfonanilides wherein the position equivalent to J is methyl and halogen substituted phenyl and since the prior art discloses on page 1744 that the replacement of the alkyl side chain on the benzenesulfonyl group by two halogen atoms gave rise to high activity. The motivation would stem from the desire to prepare other useful substituted sulfonanilides as antibacterial agents.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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